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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/068,663

02/06/2002

Chuan Li

9010

7590

10/10/2006

Chuan Li

Apt. 158

7908 Avenida Navidad

San Diego, CA 92122

EXAMINER

WALLENHORST, MAUREEN

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,663

Applicant(s)

LI, CHUAN

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48-55 is/are allowed.
- 6) ☒ Claim(s) 39-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 44-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Part c) of claim 44 is indefinite since it is not clear whether the detection assay involving the staining of the polypeptides occurs on the gel that was used for electrophoresis in part b) of the method.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizutani (US Patent no. 3,880,814).

Mizutani teaches of a composition or sample solution comprising at least three polypeptides of different known size and of different known amounts. The sample solution comprises 15 mg of the polypeptide conalbumin having a molecular weight or size of 87,000, 4

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mg of ovalbumin having a molecular weight or size of 46,000, and 7 mg of lysozyme having a molecular weight or size of 14,600. See lines 6-13 in column 4 of Mizutani. The three polypeptides in the composition taught by Mizutani are the same polypeptides as taught in Example 1 on page 11 of the instant specification, and therefore, the size of the polypeptides disclosed by Mizutani would inherently cover a range that is separable by polyacrylamide gel electrophoresis, and the amounts of the polypeptides taught by Mizutani would inherently cover a range that is detectable by a given protein detection assay.

Mizutani fails to teach that the polypeptides conalbumin, ovalbumin and lysozyme are present within a kit, and fail to teach that in preparing the solution containing the three polypeptides, the amounts of the polypeptides are estimated using a detection assay with different amounts of a standard protein such as BSA. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the polypeptides in the solution taught by Mizutani into a kit so as to have all of the polypeptides present in a single container in the correct amount in order to facilitate the quick and easy performance of the method taught by Mizutani. It also would have been obvious to one of ordinary skill in the art at the time of the instant invention to estimate the recited amounts of the polypeptides taught by Mizutani (15 mg conalbumin, 4 mg ovalbumin and 7 mg lysozyme) using a detection assay with different amounts of a standard protein such as BSA since it is common knowledge in the art of protein assays to use a standard such as BSA in different known amounts in order to determine the amounts of polypeptides in an unknown sample, and to express the amounts of the polypeptides as equivalent amounts of the standard protein, as evidenced by Applicant's own admission in the response received on February 15, 2006.

5. Claims 48-55 are allowable over the prior art of record since none of the prior art of record teaches or fairly suggests a method for estimating both the size and amount of a polypeptide in a protein sample by electrophoresing simultaneously in separate lanes on a gel the protein sample and a protein standard containing at least three different polypeptides therein having different sizes from one another and being present in different amounts from one another, wherein the amounts of the polypeptides in the standard are expressed as an equivalent amount of a standard protein, detecting the polypeptides on the gel with a detection assay to obtain the relative positions and detection intensities of the polypeptides, comparing the relative positions of the polypeptides of the protein standard with the relative position of the polypeptide in the protein sample to estimate its size, and comparing the relative detecting intensity of the polypeptides of the protein standard with the relative detecting intensity of the polypeptide in the protein sample to estimate its amount.

6. Applicant's arguments filed July 20, 2006 have been fully considered but they are not persuasive.

Applicant argues the previous rejections of the claims made in the Office action mailed on April 21, 2006 under 35 USC 102 and 35 USC 103 as being either anticipated by or obvious in view of Mizutani by stating that Mizutani fails to teach of using the polypeptides together as a protein standard to determine the size and quantity of a protein simultaneously. Applicants argue that new principles of operation have been used to develop such a method, and that the invention is not a simple mixture of polypeptides of different sizes and amounts.

In response to Applicant's arguments and evidence submitted in support thereof, it is noted that Applicant's arguments are all directed to the method of use of the protein standard.

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This method of use, as recited in instant claims 48-55, has been indicated to be allowable over the prior art of record since Applicant's new principles of operation, as outlined in the response received on July 20, 2006, are persuasive regarding this method. However, Applicant's arguments are not persuasive for claims 39-47 since claim 39 is directed simply to a product/composition containing three different size polypeptides in each of three different amounts. The composition as taught in lines 6-13 of column 4 in Mizutani is the same exact product as recited in claim 39. In addition, claim 44 is directed to a method of preparing such a product by combining three different size polypeptides in three different amounts, which is also what Mizutani teaches. It would have been obvious to one of ordinary skill in the art to determine the amounts of each of the polypeptides in the product taught by Mizutani with a detection assay by comparing the relative staining intensities of the polypeptides on a gel with the relative staining intensities of different amounts of known proteins such as BSA or lysozyme since it is common knowledge in the art of protein assays to use a standard such as BSA in different known amounts in order to determine the amounts of polypeptides in an unknown sample, and to express the amounts of the polypeptides as equivalent amounts of the standard protein, as evidenced by Applicant's own admission in the response received on February 15, 2006.

In conclusion, claims 39-47 remain rejected as set forth above, and claims 48-55 are allowable over the prior art of record.

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7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

September 19, 2006

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP ~~1000~~ 1700